Oriental Journal of Chemistry Vol. **26**(1), 269-271 (2010)

Application of sodium metaperiodate as an oxidant for the assay of *Nebivolol* in pure state and formulations

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(Received: January 15, 2010; Accepted: February 02, 2010)

ABSTRACT

A simple and sensitive spectrophotometric method by exploiting the importance of the oxidation reaction of Sodium metaperiodate for the assay of nebivolol has been described. This method is based on the oxidation of nebivolol with excess of periodate and estimating the aldehyde formed with MBTH. MBTH is used to determine aromatic[1,2], aliphatic and alicyclic amines[3]. MBTH (3-methyl-2-benzothiazolinone- hydrozone) has become an analytical tool of considerable versatility. Recoveries are almost quantitative.

Key words: Spectrophotometric method, Nebivolol, MBTH, oxidation.

INTRODUCTION

In recent years there has been growing interest in the role of sodium metaperiodate as an analytical reagent in the assay of drugs. It is a specific oxidant. Under the reaction conditions, MBTH[4] loses two electrons and one proton on oxidation, forming the electrophilic intermediate which has been postulated to the active coupling species. Azo dyes, stilbenes and schiff bases as well as pyrrole derivatives also react under oxidative conditions[5]. Nebivolol is an antihypertensive. It is long acting, cardio selective β-blocker licensed for the treatment of hypertension.

Nebivolol is α-α- [Imino bis- (methylene)] bis [6-fluro- 3,4- dihydro –2H-1-benzopyran- 2-methanol]. NEB (nebivolol) possesses iminol group, it undergoes oxidation with IO_4^- leading to the formation of an aldehyde. The aldehyde so formed reacts with in site formed intermediate resulting from MBTH through oxidation furnishing cationic dye.

EXPERIMENTAL

Instruments

An ELICO, UV- Visible spectrophotometer with 1 cm matched quartz cells were used for the spectral and absorbance measurements. An ELICO L 1-120 digital pH meter was used for pH measurements.

Chemicals and Reagents

All reagents used were of Analytical Grade and all solutions were prepared with double distilled water.

An aqueous solution of MBTH (Fluka, 0.2%, 8.55×10^{-3}M) is prepared by dissolving 200mg of MBTH as hydrochloride in 100ml distilled water. Meta-iodate solution is prepared by dissolving 200mg of sodium metaperiodate in 100ml distilled water (0.2%M, 9.35×10^{-2}M) and standardized iodometrically. Acetic acid solution (20%) is prepared by diluting 20ml of glacial acetic acid in 100ml distilled water.

Table 1: Optical, regression characteristics, precision and accuracy of the proposed methods for NEB

Parameter	IO_4^-/MBTH
λmax (nm)	620nm
Beer's law limits (µg/ml)	2 - 12
Detection limits (µg/ml)	0.2979
Molar absorptivity ($1.mol^{-1}cm^{-1}$)	0.2118×10^{5}
Sandell's sensitivity ($\mu g.cm^{-2}$/0.001 absorbance unit)	0.0191
Optimum photometric range (µg/ml)	3-10
Regression equation (Y=a+bx)	
i) Slope (b)	0.0524
ii) Standard deviation on slope (S_b)	3.4993×10^{-5}
iii) Intercept (a)	-6.000×10^{-4}
iv) Standard deviation on intercept (S_a)	5.2×10^{-3}
v) Standard Error of Estimation (S_e)	2.9277×10^{-4}
vi) Correlation co-efficient (r)	0.99999
vii) Relative standard deviation (%)*	0.4470
% Range of error (confidence limits)*	
i) 0.05 level	0.4692
ii) 0.01 level	0.7358
% Error in bulk samples**	0.3159

* average of six determinations ** average of three determinations.
Y=a+bC, where C is concentration of analyte and Y is absorbance unit

Table 2: Determination of neb in pharmaceutical formulations

Sample	Labelled amount (mg)	Amount found by Proposed Methods*	Ref. method	% Recovery by Proposed methods **
NEB	2.5	2.48±0.019 F=3.61 t=1.332	2.47±0.010	99.82±0.35
Tab 1 Tab. II	5	5.01±0.026 F=1.397 t=2.165	4.98±0.022	100.22±0.52
Tab III	5	4.98±0.017 F=2.89 t=1.237	4.99±0.01	99.97±0.2

*Tablets from four different pharmaceutical companies.
**Average ± standard deviation of six determinations, the t-and F-test values refer to comparison of the proposed method with the reference method. Theoretical values at 95% confidence limit, F=5.05,t=2.57.
***Recovery of 10mg added to the preanalysed pharmaceutical formulations (average of three determinations).

Standard Drug Solution

A 1mg/ml solution was prepared by dissolving 100mg of pure nebivolol in methanol. This stock solution was diluted stepwise with distilled water and the working standard solution of concentration 50µg-300µg/ml.

METHOD

Aliquots of standard NEB (0.5 – 3.0 ml, 100 µg/ml) solution, one ml each of ($3.740x10^{-4}$M) $NaIO_4$ and ($1.396x10^{-1}$M) acetic acid were delivered into a series of 25 ml calibrated tubes. The total volume in each tube was brought to 10 ml with distilled water and kept in boiling water bath for 40 min. After cooling to the room temperature, 1 ml ($3.424x10^{-4}$M) MBTH solution was added. After 20 min. the solution in each tube was diluted to 25 ml with distilled water. The absorbance was measured at 620 nm against a reagent blank and the amount of drug was calculated from its calibration graph.

RESULTS

The precision and accuracy of the method were tested by estimating six replicate samples of drug within the Beer's law limits. The optical characteristics are given in the Table 1. Commercial formulations were successfully analysed by the proposed method. The values obtained by the proposed method and reference methods for pharmaceutical preparations were compared statistically by the t-and F-tests and found not to differ significantly. As an additional demonstration of accuracy, recovery experiments were performed by adding a fixed amount of the drug to the preanalysed formulations. These results are presented in Table2. Recovery experiments indicated the absence of interference from the commonly encountered pharmaceutical excipients present in tablets. The proposed method is simple, sensitive and accurate and can be used for the routine quality control analysis of NEB in pure state and pharmaceutical formulations

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